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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/975,308	10/11/2001	Carl Johan Friddle	LEX-0252-USA	6999

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EXAMINER
LI, RUIXIANG

ART UNIT	PAPER NUMBER
1646	

DATE MAILED: 11/04/2002 12

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 09/975,308	Applicant(s) FRIDDLE ET AL.	
	Examiner Ruixiang Li	Art Unit 1646	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *15 October 2002* .

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-3* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-3* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

I. Status of Application, Amendments, and/or Claims

The amendment filed in Paper No. 11 on October 15, 2002 has been entered in full. Claim 3 has been added. Claims 1-3 are pending and are under consideration.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office Action.

III. 35 U.S.C. § 101

The rejection of Claims 1 and 2 under 35 U.S.C. 101, as set forth at pages 3-6 of the previous Office Action (Paper No. 10, July 8, 2002), remains.

Claims 1 and 2 and newly added Claim 3 are rejected under 35 U.S.C. § 101 because the claimed invention is not supported by either a credible, specific and substantial asserted utility or a well-established utility. The basis for this rejection is set forth at pages 3-6 of the previous Office Action (Paper No. 10, July 8, 2002).

The applicants' response (Paper No. 11, October 15, 2002; hereinafter "Response") argues that since more than half the currently marked drugs target GPCR proteins and the sequence of the present invention is related to GPCRs, the instantly claimed invention has a credible, and well-established utility (bottom of page 2 to top of page 3). This has been fully considered but is not deemed to be persuasive because the instant disclosure fails to provide any sufficient information or experimental evidence

indicating the protein with the amino acid sequence set forth in SEQ ID NO:9 is a functional GPCR protein.

The response argues that the amino acid sequence of SEQ ID NO:9 shares 99% percent identity with GenBank AB065623 shown in Exhibit C, providing a well established utility for the instantly claimed invention (2nd paragraph of page 3). This has been fully considered but is not deemed to be persuasive because the annotation for the published sequence is also based upon sequence homology and there is no sufficient and credible information that indicates the published sequence is a functional GPCR. Even if the sequence of GenBank 065623 is a GPCR, the homology of the protein of the present invention with GenBank 065623 still does not render the present invention a patentable utility because there is no single well-established utility common to all GPCRs. Rather, GPCRs vary greatly in function.

The Response argues that the instant disclosure provides a patentable utility citing various case laws (2nd paragraph of page 4 to bottom of page 5). This has been fully considered but is not deemed to be persuasive for the following reasons.

First, the Response cites a device case law (2nd paragraph of page 4). The "device" case law deals with "inopertiveness" under 101 (pertains to perpetual motion machines, for example). The claimed invention in the instant case is drawn to an isolated nucleic acid, not a device and the instant rejection under 35USC101 is not directed to inoperativeness, but to a lack of patentable utility of the claimed nucleic acid. Thus, applicants' argument citing a case law regarding a device is irrelevant to the instant case.

Second, while the FDA approval is not a prerequisite for finding a compound useful within the meaning of the patent laws and the requirement for the utility of the claimed invention is different from the FDA standard for drug approval, 35 USC §101 does require a specific, substantial, and credible utility, or well-established utility for an invention. The disclosure asserts the utility of the claimed invention in diagnosis and treatment of physiological or behavioral disorders. However, the disclosure fails to provide any evidence and information on the biological functions of the claimed molecules, and fails to identify a disorder or condition that can be diagnosed or treated with the claimed molecules. Without such sufficient information, how can one in the skilled art to use the claimed invention? See *Brenner v. Manson*, 383 U.S. 519, 148 USPQ 689 (Sup. Ct. 1966), noting that "a patent is not a hunting license. It is not a reward for the search, but compensation for its successful conclusion."

Third, 35 USC §101 requires disclosure of a specific, substantial, and credible utility. Such a patentable utility has to be a "real world " context of use which does not require significant further research. The Response confuses this requirement with the "further research and development" needed in pharmaceutical composition and drug development. In other words, a patentable utility has to be clearly identified or immediately apparent in the disclosure which has nothing to do with the "further research and development" needed in drug development. For example, determining dosage and administration routes is further research and development, which is acceptable under 35 USC 101 because it is not significant. On the other hand, determining what diseases are to be treated constitutes significant further research and development, which is not acceptable under 35 USC 101.

The Response also argues that the claimed nucleic acid sequences have utility in forensic analysis (page 5, bottom of page 5 to top of page 6). This has been fully considered but is not deemed to be persuasive because there is no specific disclosure of the population(s) that the sequence can distinguish and thus it does not provide a specific and substantial utility for the present invention.

The Response argues that DNA chips using the claimed nucleotide sequence provide a utility for the claimed invention (page 6, 2nd paragraph). This has been fully considered but is not deemed to be persuasive because such utility does not provide a specific and substantial utility for the claimed sequence. Since the disclosure does not reveal any activity/functions of the nucleotide sequence or the protein encoded by the nucleotide sequence, one skilled in the art would not know how to use the claimed invention. More importantly here, while a gene chip comprising many different sequences may have a patentable utility, that utility is not immediately conferred on the individual DNAs.

The Response further argues that the claimed polynucleotide sequence has a specific utility in mapping the protein encoding regions of the corresponding human chromosome (middle of page 7). This has been fully considered but is not deemed to be persuasive because such a utility is considered a research utility only designed to identify a particular function of the claimed molecules and is not a substantial utility. See, e.g., *Brenner v. Manson*, 383 U.S. 519, 148 USPQ 689 (Sup. Ct. 1966) wherein a research utility was not considered a "substantial utility."

The Response argues that persons of skilled in the art, as well as thousand of venture capitalists and investors, readily recognize the utility, both scientific and

commercial, of human genomic data (last paragraph of page 7) and that the usefulness of the claimed nucleic acid molecules is substantial and credible and well-established. This has been fully considered but is not deemed to be persuasive because the

disclosure has failed to provide any information or evidence on the biological functions or activities of the protein encoded by the claimed nucleic acid. Without knowing biological functions of the claimed molecules, one of skilled in the art would not know what to do with the claimed invention. Certainly, human genomic data have both scientific and commercial value. However, the commercial value does not simply render the claimed invention a specific, substantial, and credible utility, and the general utility of human genomic information does not simply render the claimed nucleic acid sequences a well-established utility.

It should be noted that the examiner has no authority to comment on the validity of the issued U.S. patents. Each application will be examined on its own merit.

In summary, the disclosure fails to provide a specific, substantial, and credible utility, or a well-established utility.

IV. Claim Rejections Under 35 U. S. C. § 112, 1st Paragraph

Claims 1-3 are rejected under 35 U. S. C. § 112, 1st paragraph. Specifically, since the claimed invention is not supported by either a specific, substantial, and credible utility, or a well-established utility, one skilled in the art clearly would not know how to use the claimed invention. The basis for this rejection is set forth at pages 3-6 of the previous Office Action (Paper No. 10, July 8, 2002).

The applicants' arguments about the patentable utility of the claimed invention has been fully considered but is not deemed to be persuasive for reasons set forth above.

V. Conclusion

No claims are allowed.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ruixiang Li whose telephone number is (703) 306-0282. The examiner can normally be reached on Monday-Friday, 8:30 am-5:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Yvonne Eyler, can be reached on (703) 308-6564. The fax phone number for this Group is (703) 305-3014 or (703) 308-4242.

Communications via Internet e-mail regarding this application, other than those under 35 U.S.C. 132 or which otherwise require a signature, may be used by the applicant and should be addressed to [yvonne.eyler@uspto.gov].

All Internet e-mail communications will be made of record in the application file. PTO employees do not engage in Internet communications where there exists a possibility that sensitive information could be identified or exchanged unless the record includes a properly signed express waiver of the confidentiality requirements of 35 U.S.C. 122. This is more clearly set forth in the Interim Internet Usage Policy published in the Official Gazette of the Patent and Trademark on February 25, 1997 at 1195 OG 89.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0196.

Ruixiang Li
Examiner
October 22, 2002

YVONNE EYLER, PH.D
SUPERVISORY PATENT EXAMINER
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